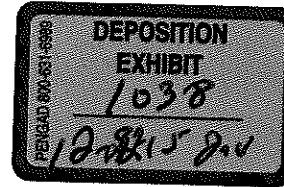


## **EXHIBIT 2**

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
 Washington, DC 20549  


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**FORM 10-K**

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**

For the fiscal year ended December 31, 2011

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 001-15989

**ENDO PHARMACEUTICALS HOLDINGS INC.**

(Exact name of registrant as specified in its charter)

Delaware  
 (State or other jurisdiction of  
 incorporation or organization)

100 Endo Boulevard Chadds Ford, Pennsylvania  
 (Address of Principal Executive Offices)

13-4022871  
 (I.R.S. Employer  
 Identification Number)

19317  
 (Zip Code)

(Registrant's Telephone Number, Including Area Code): (610) 558-9800

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of Each Class</u>	<u>Name of Each Exchange on Which Registered</u>
Common Stock of \$0.01 par value	The NASDAQ Global Select Market

Securities registered pursuant to Section 12(g) of the Act: N/A

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Sections 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every interactive data file required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months. Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐  
 (Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting common equity held by non-affiliates as of June 30, 2011 was \$4,660,596,549 based on a closing sale price of \$40.17 per share as reported on the NASDAQ Global Select Market on June 30, 2011. Shares of the registrant's common stock held by each officer and director and each beneficial owner of 10% or more of the outstanding common stock of the registrant have been excluded since such persons and beneficial owners may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive

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determination for other purposes. The registrant has no shares of non-voting common stock authorized or outstanding.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of February 17, 2012: 116,708,557

**Documents Incorporated by Reference**

Portions of the registrant's proxy statement to be filed with the SEC pursuant to Regulation 14A in connection with the registrant's 2012 Annual Meeting of Stockholders, to be filed subsequent to the date hereof, are incorporated by reference into Part III of this Form 10-K. Such proxy statement will be filed with the SEC not later than 120 days after the conclusion of the registrant's fiscal year ended December 31, 2011.

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Statements contained or incorporated by reference in this document contain information that includes or is based on “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements, including estimates of future revenues, future expenses, future net income and future net income per share, contained in the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” which is included in this document, are subject to risks and uncertainties. Forward-looking statements include the information concerning our possible or assumed results of operations. We have tried, whenever possible, to identify such statements by words such as “believes,” “expects,” “anticipates,” “intends,” “estimates,” “plan,” “projected,” “forecast,” “will,” “may” or similar expressions. We have based these forward-looking statements on our current expectations and projections about the growth of our business, our financial performance and the development of our industry. Because these statements reflect our current views concerning future events, these forward-looking statements involve risks and uncertainties. Investors should note that many factors, as more fully described in Item 1A under the caption “Risk Factors” in this document, supplement, and as otherwise enumerated herein, could affect our future financial results and could cause our actual results to differ materially from those expressed in forward-looking statements contained or incorporated by reference in this document.

We do not undertake any obligation to update our forward-looking statements after the date of this document for any reason, even if new information becomes available or other events occur in the future. You are advised to consult any further disclosures we make on related subjects in our reports filed with the Securities and Exchange Commission (SEC). Also note that, in Item 1A, we provide a cautionary discussion of the risks, uncertainties and possibly inaccurate assumptions relevant to our business. These are factors that, individually or in the aggregate, we think could cause our actual results to differ materially from expected and historical results. We note these factors for investors as permitted by Section 27A of the Securities Act and Section 21E of the Exchange Act. You should understand that it is not possible to predict or identify all such factors. Consequently, you should not consider this to be a complete discussion of all potential risks or uncertainties.

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Endo Pharmaceuticals Holdings Inc., which we refer to as “Endo”, “we”, “us”, or the “Company”, is a U.S. based, specialty healthcare solutions company focused on branded and generic pharmaceuticals, devices and services. We have redefined our position in the healthcare marketplace by anticipating and embracing the evolution of health decisions based on the need for high-quality and cost-effective care. We aim to be the premier partner to healthcare professionals and payment providers, delivering an innovative suite of complementary branded and generic drugs, devices, services and clinical data to meet the needs of patients in areas such as pain management, urology, oncology and endocrinology.

In June 2011, we acquired American Medical Systems Holdings, Inc. (AMS), a leading provider of devices and therapies for treating male and female pelvic health conditions. The acquisition of AMS strengthens our leading core urology franchise and expands our presence in the medical devices market. In November 2010, we acquired Generics International (US Parent), Inc. (doing business as Qualitest Pharmaceuticals, which we refer to herein as Qualitest), a leading U.S. based privately-held generics company and currently the sixth largest U.S. generics company, as measured by prescriptions filled during 2011. Qualitest is focused on cost-competitive, high-quality manufactured products with cost advantages or with high barriers to entry. In September 2010, we acquired our partner on Opana® ER, Penwest Pharmaceuticals Co. (Penwest), a drug delivery company focused on applying its drug delivery technologies and drug formulation expertise to the formulation of its collaborators' product candidates under licensing collaborations. In July 2010, we acquired HealthTronics, Inc. (HealthTronics), a provider of healthcare services and manufacturer of certain related medical devices, primarily for the urology community. In February 2009, we completed our acquisition of Indevus Pharmaceuticals, Inc. (now, Endo Pharmaceuticals Solutions Inc., which we refer to herein as Indevus), a specialty pharmaceutical company engaged in the acquisition, development and commercialization of products to treat conditions in urology, endocrinology and oncology. As a combined company, we expect to deliver more comprehensive healthcare solutions across our diversified businesses in four key segments, Branded Pharmaceuticals, Generics, Devices and Services in key therapeutic areas including pain and urology.

We have a portfolio of branded pharmaceuticals that includes established brand names such as Lidoderm®, Opana® ER, Voltaren® Gel, Percocet®, Frova®, Supprelin® LA, Vantas®, Valstar® and Fortesta® Gel. Branded products comprised approximately 61% of our total revenues in 2011. Our non-branded generic portfolio, which accounted for 21% of total revenues in 2011, currently consists of products primarily focused in pain management. We generally focus on selective generics that have one or more barriers to market entry, such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing. Device revenue accounted for 11% of total revenues in 2011 and our services segment accounted for the remaining 2011 revenue. We generated total revenues of \$2.73 billion for the year ended December 31, 2011.

Financial information presented herein reflects the operating results of Indevus from February 23, 2009, HealthTronics from July 2, 2010, Penwest from September 20, 2010, Qualitest from November 30, 2010 and AMS from June 18, 2011.

On a continuous basis, we evaluate and, where appropriate, pursue acquisition opportunities. In particular, we look to continue to enhance our product line by acquiring or licensing rights to additional products and compounds and therefore regularly evaluate selective acquisition and license opportunities. Such acquisitions or licenses may be effected through the purchase of assets, joint ventures and licenses or by acquiring other companies.

Our wholly-owned subsidiary, Endo Pharmaceuticals Inc. (EPI), commenced operations in 1997 by acquiring certain pharmaceutical products, related rights and assets of The DuPont Merck Pharmaceutical

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Company, which subsequently became DuPont Pharmaceuticals Company and was thereafter purchased by the Bristol-Myers Squibb Pharma Company in 2001. EPI was formed by certain members of the then-existing management of DuPont Merck and an affiliate of Kelso & Company who were also parties to the purchase agreement under which we acquired these initial assets.

We were incorporated in Delaware as a holding company on November 18, 1997 and have our principal executive offices at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317 (telephone number: (610) 558-9800).

**Our Strategy**

Our core strategy is to continue to build a healthcare solutions company to improve outcomes for patients, providers, and payers and respond to changing economics. We strive to enable better care by redefining healthcare value. The execution of our strategy will enable us to be the premier partner to healthcare professionals and payment providers, delivering an innovative suite of complementary branded and generic drugs, devices, services and clinical data to meet the needs of patients in areas such as pain management, urology, oncology and endocrinology.

Over the past three years, we have evolved from a product-driven pharmaceutical company to a healthcare solutions provider with an integrated business model that includes both branded and generic prescription drugs, medical devices and healthcare services. Our diversified business across therapeutic areas with a core focus in pain management and urology enables us to strengthen our partnerships with patients, providers, and payers by offering multiple products and platforms to deliver healthcare solutions. For example, our recent acquisitions have had or are expected to have the following results:

- In February 2009, we acquired Indevus, which helped us expand beyond our legacy pain management business and secured a position in urology;
- In July 2010, we acquired HealthTronics, which gave us an established presence in the healthcare services space and added critical mass in urology;
- In September 2010, we acquired Penwest, which strengthened our pain management franchise by enhancing flexibility around our product Opana® ER;
- In November 2010, we acquired Qualitest, which enhanced our solutions platform with the addition of a comprehensive generics business, adding critical mass to our existing generics business while also strengthening our pain management franchise offerings. The combined generics business has approximately 50 abbreviated new drug applications (ANDAs) under active FDA review in multiple therapeutic areas, including pain management, urology, central nervous system (CNS) disorders, immunosuppression, oncology, women's health and hypertension, among others; and
- In June 2011, we acquired AMS, which furthered Endo's evolution from a pharmaceutical product-driven company to a healthcare solutions provider, strengthened our core urology franchise and expanded our presence in the medical devices market.

We believe that recent healthcare reform in the U.S. places a premium on providing cost-effective healthcare solutions like those we offer. Applying the technology platforms of our recent acquisitions to Endo's already substantial business holds the potential for significant advantages in the new healthcare environment that will enhance our product offerings and accelerate growth.

See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Annual Report on Form 10-K for further discussion.



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**Table of Contents****Our Competitive Strengths**

To successfully execute our strategy, we must continue to capitalize on our following core strengths:

***Proactive anticipation of the evolution of healthcare delivery in the U.S. by diversifying our business away from that of a product-driven pharmaceutical company to that of a healthcare solutions provider.*** In light of the evolving healthcare industry, we have executed a number of corporate acquisitions in 2010 and 2011 to diversify our business and become a healthcare solutions provider with an integrated business model that includes both branded and generic prescription drugs, as well as medical devices and healthcare services. This diversification will enable us to provide customers with quality outcomes and economic value and offer unique solutions along targeted disease care pathways. As a result of recent strategic actions combined with strategic investments in our core business, we have redefined our position in the healthcare marketplace and successfully reduced the revenue concentration of Lidoderm®. Lidoderm® contributed approximately 30% of our business' revenue in 2011, compared to 46% and 52% in 2010 and 2009, respectively. Our acquisitions of AMS, Qualitest and HealthTronics have also contributed to our diversification. The acquisition of Qualitest has enabled us to gain critical mass in our generics business. Through HealthTronics and AMS, we provide healthcare services and manufacture medical devices, primarily for the urology community.

***Established portfolio of branded products.*** We have assembled a portfolio of branded prescription products to treat and manage pain. In addition, as a result of our acquisition of Indevus, we have added several branded products to treat conditions in urology and endocrinology. Our branded products include: Lidoderm®, Opana® ER, Voltaren® Gel, Percocet®, Frova®, Supprelin® LA, Vantas®, Valstar® and Fortesta® Gel. For a more detailed description of each of our products, see "Product Overview."

***Focused pipeline.*** As a result of our focused research and development efforts, we believe we have a promising development pipeline and are well-positioned to capitalize on our core development products. Currently, our core development pipeline consists of one NDA filed with the FDA and two products in Phase III trials. We have also initiated development efforts for medical devices and have multiple programs at concept and development stages across urology, uro-oncology, endocrinology and urogynecology. For a more detailed description of our development pipeline, see "Select Products in Development."

***Research and development expertise.*** Our research and development efforts are focused on the development of a balanced, diversified portfolio of innovative and clinically differentiated products. We are continuously seeking opportunities that deepen our presence in the pain management area as well as in the areas of oncology, urology and endocrinology. We will continue to capitalize on our core expertise with analgesics and expand our abilities to both capture earlier-stage opportunities and pursue other therapeutic areas. Through our acquisition of AMS, we have expanded our expertise in the development of medical devices. Through our Qualitest business, we have increased our efforts to seek out and develop generic products with complex formulations and high barriers to entry. We continue to invest in research and development because we believe it is critical to our long-term competitiveness. At December 31, 2011, our research and development and regulatory affairs staff consisted of 445 employees, based primarily in Westbury, New York, Minnetonka, Minnesota, San Jose, California, Huntsville, Alabama, and at our corporate headquarters in Chadds Ford, Pennsylvania. Our research and development expenses, including upfront and milestone payments were \$182.3 million in 2011, \$144.5 million in 2010 and \$185.3 million in 2009.

We have assembled an experienced and multi-disciplined research and development team of scientists and technicians with drug discovery and development expertise, medical device design and development expertise, and broad experience in working with the FDA. To supplement our internal efforts, we engage the services of various independent research organizations, physicians and hospitals to conduct and coordinate our preclinical and clinical studies to establish the safety and effectiveness of new products.

***Targeted national sales and marketing infrastructure.*** We market our branded products directly to physicians through a sales force of over 1,000 employees in the pharmaceutical products, devices and services



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markets. This sales force consists of 450 Endo pharmaceutical sales representatives and 228 sales contracted representatives focusing primarily on pain products, 79 Endo sales representatives focusing primarily on bladder and prostate cancer products, 35 Endo medical center representatives focusing on the treatment of central precocious puberty and 27 Endo account executives focusing on managed markets customers. We also have 361 sales representatives focusing primarily on devices and 39 on services. We market our products and services to primary care physicians and specialty physicians, including those specializing in pain management, orthopedics, neurology, rheumatology, surgery, anesthesiology, urology and pediatric endocrinology. Our sales forces also target retail pharmacies and other healthcare professionals throughout the U.S. We distribute our products principally through independent wholesale distributors, but we also sell directly to retailers, clinics, government agencies, doctors and retail and specialty pharmacies. Our marketing policy is designed to assure that products and relevant, appropriate medical information are immediately available to physicians, pharmacies, hospitals, public and private payers, and appropriate healthcare professionals throughout the U.S. We work to gain access to healthcare authority, pharmacy benefit managers and managed care organizations' formularies (lists of recommended or approved medicines and other products), including Medicare Part D plans and reimbursement lists by demonstrating the qualities and treatment benefits of our products within their approved indications.

***Expanding focus on generic products.*** Our generics business has approximately 50 ANDAs under active FDA review in multiple therapeutic areas, including pain management, urology, CNS disorders, immunosuppression, oncology, women's health and hypertension, among others. We develop generic products including those that involve significant barriers to entry such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing. We believe products with these characteristics will face a lesser degree of competition and therefore provide longer product life cycles and higher profitability than commodity generic products. Our business model continues to focus on being the lowest-cost producer of products in categories with high barriers to entry and lower levels of competition. Our generics business is focused in categories where there are fewer challenges from low-cost operators in markets such as China and India, with approximately 36% of our product portfolio being comprised of controlled substances, which cannot be manufactured off-shore and imported into the U.S. In addition, approximately 15% of our product portfolio is made up of liquids, which are uneconomical to ship into the U.S. We expect to continue to improve our overall profitability by optimizing our portfolio for high volume and growth while strengthening our U.S. generics competitive position, product pipeline, portfolio and capabilities.

***Manufacturing and distributing medical devices.*** Through our AMS subsidiary, we manufacture medical devices for various pelvic health disorders. Specifically, the AMS business includes a diverse product portfolio that treats men's incontinence, erectile dysfunction, benign prostatic hyperplasia (BPH), women's incontinence and pelvic floor repair. These devices strengthen our leading core urology franchise, where we remain focused on expanding the markets for our products because the portion of afflicted patients seeking treatment remains relatively low. When patients seek treatment, they generally begin with options that will be as minimally invasive as possible, such as pharmaceutical therapies. Also, when patients initially seek treatment, their first physician contact is usually with a general practitioner and not with a surgical specialist. If less invasive options have proven unsuccessful, patients and their physicians may consider surgery as a solution. Sales of these products benefit from an aging population with a desire to maintain a high quality of life, the expanding availability of safe and effective treatments, minimally invasive solutions and increasing patient and physician awareness of these treatments.

***Providing healthcare services.*** Through our HealthTronics subsidiaries, we provide healthcare services and manufacture certain related medical devices, primarily for the urology community. Specifically, the HealthTronics business and applicable services include lithotripsy services, a medical procedure where a device called a lithotripter transmits high energy shockwaves through the body to break up kidney stones, prostate treatment services for benign and cancerous conditions of the prostate, laboratory services, known as anatomical pathology services, for urologists, electronic medical records services and medical products manufacturing, sales, and maintenance.

***Strong balance sheet and significant cash flow.*** We have historically generated significant cash flow from operating activities due to a unique combination of strong brand equity, attractive margins and low capital

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expenditures. For the year ended December 31, 2011, we generated \$702.1 million of cash from operations. We expect that sales of our currently marketed products, devices and services will allow us to continue to generate significant cash flow from operations in the future. We maintain a strong balance sheet with moderate leverage levels and ample liquidity, which gives us flexibility to make strategic investments in our business. As of December 31, 2011, we had \$566.7 million of cash and marketable securities, up to \$500 million of availability under the Revolving Credit Facility, and availability of up to \$500 million of additional revolving or term loan commitments.

***Experienced and dedicated management team.*** Our senior management team has a proven track record of building businesses through internal growth as well as through licensing and acquisitions. Their expertise has contributed to our success in identifying, consummating and integrating such acquisitions. Members of our management team have consummated five significant acquisitions since 2009 (AMS, Qualitest, Penwest, HealthTronics and Indevus) and have received FDA approval on more than twenty new products and product line extensions since 1997. As a result of several successful product launches and our strategic acquisitions, we have grown our total revenues from \$108 million in 1998 to over \$2.7 billion in 2011.

**Our Areas of Focus*****Pain Management Market***

According to IMS Health data, the total U.S. market for pain management pharmaceuticals, excluding over-the-counter products, totaled \$23.9 billion in 2011. This represents an approximate 7% compounded annual growth rate since 2007. Our primary area of focus within this market is analgesics and, specifically, opioid analgesics. In 2011, analgesics were the third most prescribed medication in the U.S. with nearly 312 million prescriptions written for this classification.

Opioid analgesics is a segment that comprised approximately 78% of the analgesic prescriptions for 2011 and represented almost 53% of the overall U.S. pain management market. Total U.S. sales for the opioid analgesic segment were \$8.4 billion in 2011, representing a compounded annual growth rate of 5% since 2007. With the launch of Voltaren® Gel in 2008, Endo gained presence in the osteoarthritis market competing in the analgesic non-narcotic and anti-arthritic classes which together had over 191 million prescriptions written in 2011, representing 41% of the U.S. pain management market. The U.S. sales for the analgesic non-narcotic and anti-arthritic markets were \$15.5 billion with a compound annual growth rate of 8% since 2007.

Opioid analgesic products are used primarily for the treatment of pain associated with orthopedic fractures and sprains, post herpetic neuralgia, back injuries, migraines, joint diseases, cancer and various surgical procedures.

The growth in this segment has been primarily attributable to:

- increasing physician recognition of the need and patient demand for effective treatment of pain;
- aging population (according to the U.S. Census Bureau, from 2000 to 2010 the population aged 65 and older reached 40 million people, representing 15% growth over this period);
- introduction of new and reformulated branded products; and
- increasing incidence of chronic pain conditions, such as cancer, arthritis and low back pain.

***Urology, Endocrinology and Oncology Markets***

Through our acquisition of Indevus as well as other business development activities, Endo entered the urology, endocrinology and oncology markets, specifically the prostate cancer therapeutic area with Vantas®, the bladder oncology space with Valstar® and Urocidin™, and the central precocious puberty therapeutic area with

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Supprelin® LA. With our early 2011 launch of Fortesta® Gel, which was approved by the FDA in December 2010 for the treatment of hypogonadism, we entered the testosterone replacement therapy (TRT) market. We anticipate increasing our presence in this market through our development product Aveed™. As a result of our acquisition of HealthTronics, we now offer a full suite of urology products and services with the addition of lithotripsy, BPH and prostate cancer therapies, as well as anatomical pathology services for the detection and diagnosis of cancer and other conditions from our HealthTronics subsidiary. As a result of our acquisition of AMS, we now offer a broad array of medical devices which deliver innovative medical technology solutions to physicians treating male incontinence, erectile dysfunction, female incontinence, pelvic floor repair and BPH.

*Central Precocious Puberty (CPP)*

In a recent study, the incidence of CPP reported from national registries in the European Union subdivided by gender and age at diagnosis was approximately 1 per 10,000 in girls who were younger than 4 years, thereafter gradually rising to 8 per 10,000 for girls aged 5 to 9 years. The incidence in boys younger than 8 years was approximately 1 per 10,000. Recent market research indicates that girls in the U.S. are physically maturing at an earlier age than they did 30 years ago, and the number of girls diagnosed with precocious puberty is on the rise. In the U.S., 6,000 patients are estimated to have CPP with approximately 2,000 diagnosed annually. CPP is treated by pediatric endocrinologists in the U.S. where there are approximately 790 practicing pediatric endocrinologists. In 2011, the market for drugs to treat CPP, reported by IMS Health NSP, was approximately \$125 million in the U.S.

*Prostate cancer*

Prostate cancer is the most common cancer for men and the second leading cause of cancer deaths in men. According to the American Cancer Society, every year approximately 240,000 men in the U.S. are diagnosed with prostate cancer and 30,000 die from this disease.

*Bladder cancer*

There are more than 500,000 people in the U.S. alive with a history of bladder cancer, which is the third most common cancer among men and the eleventh most common among women in the U.S. The American Cancer Society estimated approximately 73,510 new cases of bladder cancer and 14,880 deaths from this disease in the U.S. in 2011. The 2012 estimate is expected to be similar. Rates of bladder cancer are expected to increase due to the aging population; nearly 90% of cases of bladder cancer are diagnosed in people age 55 or older. The number of patients in the total non-invasive bladder cancer population will thus increase due to the rising incidence as well as high recurrence rates, leading to a substantial prevalent population.

*BCG-refractory CIS bladder cancer*

CIS of the urinary bladder is a rare form of bladder cancer, affecting about 10 of every 100 patients diagnosed with bladder cancer. Standard treatment of CIS of the urinary bladder is transurethral resection of the

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bladder tumor, followed by one or two courses of immunotherapy with the vaccine BCG. About 50 percent of patients will become refractory to BCG therapy. Valstar® intravesical therapy is the only FDA-approved treatment of carcinoma in situ of the urinary bladder in patients who are refractory to BCG immunotherapy when cystectomy – or bladder removal – is not an option.

*Testosterone replacement overview*

In the U.S. alone, it is estimated that 13.8 million men have low testosterone levels; however, only about 9% are currently being treated. Hypogonadism, or low testosterone, is under diagnosed and under treated. Factors contributing to this include a lack of screening for low testosterone and the perceived risk of prostate cancer associated with current treatment strategies. In the U.S., TRT sales have dramatically increased, from approximately \$552 million in 2006 to over \$1.6 billion in 2011, representing a compounded annual growth rate of 24% since 2006.

*Male incontinence*

We estimate over 50 million men worldwide suffer from urinary incontinence, the involuntary release of urine from the body. Male incontinence may be managed with a catheter and leg bag to collect urine, or with pads and diapers to absorb the leaks. These measures are far from ideal, as they come with recurring replacement product costs, the potential for infection, embarrassing leaks and odor, a significantly diminished quality of life, and may even result in the need for managed care.

*Erectile dysfunction*

Erectile dysfunction is the inability to achieve or maintain an erection sufficient for sexual intercourse. It is most often caused by vascular disease, complications from diabetes, or prostate surgery which can damage both nerves and arteries necessary for erectile function. This disease can also be caused by spinal cord injury, and may have a psychogenic component. We estimate that erectile dysfunction may affect over 400 million men and their partners around the world. The primary treatment for erectile dysfunction is the class of drugs referred to as PDE-5 inhibitors. Approximately 30 percent of patients using these drugs do not have a positive response. If such drugs are not effective, the patient may elect to have an implant of one of our penile prosthesis products, which provide consistent, reliable solutions.

*Female incontinence*

We estimate over 500 million women worldwide suffer from urinary or fecal incontinence. These diseases can lead to debilitating medical and social problems, ranging from embarrassment to anxiety and depression. There are three types of urinary incontinence: stress, urge, and mixed incontinence (a combination of stress and urge). While stress incontinence is generally caused by a weakening of the pelvic floor and resultant hypermobility of the urethra, urge incontinence is more complex and currently not as well understood. Pads and diapers are often used to contain and absorb leaks, and may be acceptable for controlling mild incontinence. Drug therapy and electrical nerve stimulation are currently used to treat urge incontinence. Incontinence may be treated through exercises to strengthen pelvic floor muscles, or through the injection of collagen or some other bulking agent into the wall of the urethra or bladder neck to narrow the passage. Surgical solutions are generally recommended only when these other therapies are not effective. Our current products in the market treat stress incontinence, which generally results from a weakening of the tissue surrounding the bladder and urethra which can be a result of pregnancy, childbirth and aging.

*Pelvic floor repair*

Pregnancy, labor, and childbirth are some of the primary causes of pelvic floor prolapse and other pelvic floor disorders. Prolapse and other pelvic floor defects may be treated with a variety of open, laparoscopic, and

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transvaginal surgeries. We estimate over 400,000 procedures are performed annually around the world to repair some form of pelvic floor prolapse in women. These procedures have historically been performed through the use of suture and graft materials designed for other surgical applications. We offer less invasive solutions for pelvic floor repair.

*BPH therapy*

Our products can be used to relieve restrictions on the normal flow of urine from the bladder caused by bladder obstructions, generally the result of BPH or bulbar urethral strictures. Symptoms of BPH include increased urination frequency, sudden urges to urinate, and weak urine flow. More than 70 percent of men over age 60 have some symptoms of BPH. Prior to the development of less invasive therapies, the conventional treatment for those experiencing a physical obstruction of the prostatic urethra was a surgical removal of the prostatic tissue performed under general anesthesia, known as a transurethral resection of the prostate (TURP). We offer men an alternative to a TURP, using laser therapy designed to reduce the comorbidities associated with TURP. This laser system has paved the way for creating a new standard of care in the treatment of BPH.

For those men not yet to the point of urethral obstruction, but for whom symptomatic relief is desired, a less-invasive tissue ablation technique can be performed in a physician's office using microwave energy delivered to the prostate. The market for an office-based therapy for BPH has remained relatively flat, at approximately 100,000 men treated annually, partially due to the continued adoption of laser delivered BPH treatments.

***Medical Services Markets***

Through our HealthTronics business, we provide services in the following areas:

*Lithotripsy services*

We provide lithotripsy services, which is a medical procedure where a device called a lithotripter transmits high energy shockwaves through the body to break up kidney stones. Our lithotripsy services are provided principally through limited partnerships and other entities that we manage, which use lithotripters. In 2011, physicians who are affiliated with us used our lithotripters to perform approximately 50,000 procedures in the U.S. As the general partner of limited partnerships or the manager of other types of entities, we also provide services relating to operating our lithotripters, including scheduling, staffing, training, quality assurance, regulatory compliance, and contracting with payors, hospitals, and surgery centers.

*Prostate treatment services*

We provide treatments for benign and cancerous conditions of the prostate. In treating benign prostate disease, we deploy three technologies: (1) photo-selective vaporization of the prostate (PVP), (2) trans-urethral needle ablation (TUNA), and (3) trans-urethral microwave therapy (TUMT) in certain partnerships. All three technologies apply an energy source which reduces the size of the prostate gland. For treating prostate and other cancers, we use a procedure called cryosurgery, a process which uses lethal ice to destroy tissue such as tumors for therapeutic purposes. We also manufacture both the medical devices and related consumables utilized in cryosurgery operations, and also provide cryosurgery treatments. Our prostate treatment services are provided principally by us using equipment that we lease from limited partnerships and other entities that we manage. We also provide services relating to operating the equipment, including scheduling, staffing, training, quality assurance, regulatory compliance, and contracting.

*Anatomical pathology services*

We provide anatomical pathology services primarily to the urology community. We have one pathology lab located in Georgia, HealthTronics Laboratory Solutions that provides laboratory detection and diagnosis services to urologists throughout the U.S. In addition we manage pathology laboratories for physician practice groups



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located in Texas, Florida and Pennsylvania. Through HealthTronics Laboratory Solutions, we also provide administrative services to in-office pathology labs for practice groups and provide pathology services to physicians and practice groups with our lab equipment and personnel at our HealthTronics Laboratory Solutions laboratory sites.

*Medical products manufacturing, sales and maintenance*

We manufacture and sell medical devices focused on minimally invasive technologies for tissue and tumor ablation through cryoablation, which is the use of lethal ice to destroy tissue, such as tumors, for therapeutic purposes. We develop and manufacture these devices for the treatment of prostate and renal cancers and we believe that our proprietary technologies have broad applications across a number of markets, including the ablation of tumors in the lung and liver and palliative intervention (treatment of pain associated with metastases). We also manufacture the related spare parts and consumables for these devices. We also sell and maintain lithotripters and related spare parts and consumables.

*Information Technology Solutions*

In the second half of 2011, as part of our effort to increase and broaden the relationships within the urology community, we acquired two electronic medical records software companies, Intuitive Medical Software, LLC and meridianEMR, Inc., which provide electronic medical records for urologists. Together, these acquisitions provide access to approximately 1,850 urologists using data platforms that will enhance service offerings in urology practice management.

**Products Overview*****Branded Pharmaceuticals***

The following table summarizes select products in our branded portfolio:

<b><u>Branded Pharmaceuticals</u></b>	<b><u>Active Ingredient(s)</u></b>	<b><u>Status</u></b>
Lidoderm®	lidocaine 5%	Marketed
Opana® ER(1)	oxymorphone hydrochloride	Marketed
Opana®	oxymorphone hydrochloride	Marketed
Percocet®	oxycodone hydrochloride and acetaminophen	Marketed
Voltaren® Gel(2)	diclofenac sodium topical gel 1%	Marketed
Frova®(3)	frovatriptan succinate	Marketed
Supprelin® LA	histrelin acetate	Marketed
Vantas®	histrelin acetate	Marketed
Valstar®	valrubicin	Marketed
Fortesta® Gel(4)	2% testosterone	Marketed

- (1) Licensed marketing and development rights from Grünenthal GmbH.
- (2) Licensed marketing rights from Novartis Consumer Health, Inc.
- (3) Licensed marketing rights from Vernalis Development Limited.
- (4) Licensed marketing and development rights from Strakan International Limited.

**Lidoderm®.** Lidoderm® (lidocaine patch 5%) was launched in September 1999. A topical patch product containing lidocaine, Lidoderm® was the first FDA-approved product for the relief of the pain associated with post-herpetic neuralgia, a condition thought to result after nerve fibers are damaged during a case of Herpes Zoster (commonly known as shingles). Lidoderm® is also currently protected by Orange Book-listed patents for, among other things, a method of treating post-herpetic neuralgia and the composition of the lidocaine-containing patch. The last of these patents is set to expire in 2015. In 2011, 2010 and 2009, Lidoderm® net sales were \$825.2 million, \$782.6 million and \$763.7 million, respectively. Lidoderm® accounted for approximately 30% of our 2011 total revenues.